IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

SHANON SCHMIDTKNECHT individually and WILLIAM SCHMIDTKNECHT individually and as Special Administrator of the Estate of COLE SCHMIDTKNECHT *Plaintiffs,* v. OPTUMRX RX, INC., et al. *Defendants*.	CIVIL ACTION CASE NO: 1:25-cv-0093-BBC **JURY TRIAL DEMANDED**

ORDER

AND NOW this _____ day of _____, 2025, upon consideration of Defendant OptumRx, Inc.'s Motion to Dismiss Plaintiffs' First Amended Civil Action Complaint, and Plaintiffs' response in opposition thereto, it is hereby **ORDERED** that said Motion is **DENIED**.

BY THE COURT:

_____
Hon. Byron B. Conway
U.S. District Judge

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PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT OPTUMRX, INC.'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CIVIL ACTION COMPLAINT

Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually and as Special Administrator of the Estate of Cole Schmidtknecht, through undersigned counsel, hereby respond in opposition to Defendant OptumRx, Inc.'s Motion to Dismiss Plaintiffs' First Amended Civil Action Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted. The grounds for Plaintiffs' opposition are set forth in the concurrently filed Memorandum in Opposition to Defendant OptumRx, Inc.'s Motion to Dismiss the first Amended Civil Action Complaint, and for the reasons set forth therein, Plaintiffs respectfully request that the Motion be denied.

Respectfully submitted,

Date: April 11, 2025 By: _____

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PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT OPTUMRX'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

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INTRODUCTION

Defendant OptumRx's Motion to Dismiss rests on an overly broad reading of ERISA preemption and overlooks the independent legal duties pharmacy benefit managers owe under Wisconsin law. This case is not about plan design, benefits entitlement, or claims administration under an ERISA plan. It arises from defendant OptumRx's extracontractual conduct – its failure to provide adequate notice of formulary changes, facilitate access to alternative medications, and price critical asthma medication fairly – all of which constitute breaches of independent statutory and common law duties aimed at protecting patient safety. Such conduct is not immunized by ERISA, and longstanding precedent makes clear that preemption does not apply where liability does not depend on interpreting plan terms.

OptumRx's challenge to plaintiffs' negligence per se claims is equally unavailing. The statutes at issue were enacted to ensure continuity of care and protect patients from dangerous coverage disruptions – precisely the type of harm that occurred here. These violations provide a valid basis for liability under Wisconsin law.

For all of these reasons, as described in detail below, the Motion to Dismiss should be denied.

FACTUAL BACKGROUND

On January 10, 2024, Cole Schmidtknecht, a 22-year-old who had suffered from asthma since infancy, went to his local Walgreens pharmacy to refill his prescription for Advair Diskus, an inhaler that had successfully controlled his asthma for decades. *See* Amended Complaint, attached as Exhibit "A," ¶¶ 48-49. He was informed for the first time that his insurance no longer covered Advair Diskus and it would cost him $539.19 out of pocket. *Id*., ¶¶ 54-55. Unable to afford this unexpected expense, Cole left the pharmacy without his preventative inhaler. *Id*., ¶ 72.

Five days later, on January 15, 2024, Cole had a severe asthma attack and was taken to the hospital. *Id*., ¶ 79. Six days later he was dead. *Id*., ¶¶ 80-87.

Cole died because of the negligence of OptumRx, the pharmacy benefits manager ("PBM") of his health insurance plan, and Walgreens (which is not at issue in this motion). He died because OptumRx never told him that it would no longer cover Advair Diskus, the life sustaining medication on which he had depended for decade, nor would it cover its generic equivalents. This failure to inform Cole was especially harmful because, by excluding his existing drug or its generic equivalent, and mandating that Cole switch to a different ***brand*** drug, OptumRx guaranteed that Cole would be forced to leave the pharmacy without his life-sustaining medication. Under Wisconsin law, pharmacists have discretion to substitute a generic drug for a brand, but could not substitute OptumRx's newly "approved" brand for the newly excluded brand, Advair Diskus, without approval of the prescribing physician. *Id*., ¶¶ 31-33. Under OptumRx's new regimen, Cole could only obtain Advair Diskus by going through a Prior Authorization process which typically takes at least 72 hours to complete. *Id*., ¶¶ 25-27.

OptumRx gave Cole no notice whatsoever of these new requirements, ensuring that when he went to the pharmacy to refill a medication he had taken for nearly a decade, he would not receive his life-sustaining preventative inhaler unless he could afford the new price -- $539. And it was OptumRx who dictated this $539 price, even though, in 2023, Advair Diskus would cost Cole no more than about $66.86, even during the deductible phase of coverage. *Id*., ¶¶ 52, 113.

The Wisconsin legislature was well aware that these abuses can occur and enacted legislation to protect its residents from them. The legislation requires:

- at least thirty (30) days advance notice of any formulary change that removes a drug from their formulary tier, to give enrollees the chance to request an exception to the formulary change. Wis. Stat. § 632.861(4).

- that any Step Therapy Protocol be "derived from peer-review publications, evidence-based research, and widely accepted medical practice, and be described on its internet site. Wis. Stat. § 632.866(2)(a), (c).

- that a PBM not impose a price greater than the amount the enrollee would pay without insurance. Wis. Stat. § 632.861(3).

These statutory requirements mirror the common law standard of care for PBMs. OptumRx's own Provider Manual recognizes that it should:

- reach out to patients impacted by formulary changes with the information they need, including suggested covered alternative medications, and support its patients through this process. *Id*., ¶ 40.

- only require Prior Authorizations for drugs that may not be medically necessary. *Id*., ¶ 37.

OptumRx violated not only Wisconsin statutes, but also its own standards of care when it failed to notify Cole of these formulary changes and required prior authorization for Advair Diskus, a drug it had previously covered as medically necessary.

In 2023, Cole began working for Kriete Truck Center Green Bay, where he earned a modest hourly wage. *Id*., ¶ 50. In August of 2023, Cole switched from his parent's benefit plan to Kriete Trucking's fully insured plan administered by United Health. *Id*., ¶ 51. Under this plan, OptumRx was the PBM for Cole's medications. *Id*. Cole's prescription for Advair Diskus had historically been covered by this insurance. *Id*., ¶ 52. Under the United Health-OptumRx plan in 2023, Advair Diskus cost Cole no more than about $66.86, even during the deductible phase of coverage, or about $35 during the covered phase. *Id*.

As of January 1, 2024, Cole's employer, Kriete Trucking, adopted a self-insured plan and contracted with UMR, a United Health subsidiary, to administer it with OptumRx to continue as PBM. *Id*., ¶ 53. By November 2023, OptumRx had already decided to exclude both Advair Diskus and its generic equivalents from its formularies starting in 2024. *Id*., ¶ 56. There was no medical reason for this decision, OptumRx made it so they could get kickbacks from manufacturers of

other asthma medications. *Id*., ¶¶ 24, 31, 32, 44, 45, 63. Likewise, by November 2023, OptumRx had decided to require patients to undergo step therapy prior to receiving Advair Diskus or its generic equivalents starting in 2024, even if, as with Cole Schmidtknecht, they had taken Advair Diskus for years and it controlled their asthma. *Id*., ¶ 57.

OptumRx could have structured its formulary to only require step therapy for patients new to Advair Diskus, or to cover its generic equivalent, but did neither in order to line its pockets with rebate money for branded drugs. *Id*., ¶¶ 30-34. Cole had been on two United Health plans with OptumRx acting as the PBM beforehand. *Id*., ¶ 59. OptumRx knew that these exclusionary actions would put patients like Cole at risk, yet did nothing to warn him about ***any*** formulary changes. *Id*., ¶¶ 25-37, 60. As a result, Cole did not have the opportunity to challenge the decision, request an exemption, or make arrangements with his physician to switch the prescription to a covered medication. *Id*., ¶¶ 39, 42, 58-62. Also contrary to Wisconsin law, OptumRx did not post the process and criteria for its new mandatory step therapy protocol for Advair Diskus patients on its website before requiring Cole and similar patients to switch from Advair Diskus. *Id*., ¶¶ 47, 63.

Plaintiffs commenced this action against OptumRx and Walgreens on January 21, 2025. On March 11, 2025, after OptumRx filed a motion to dismiss, plaintiffs filed an Amended Complaint against defendants OptumRx, Walgreen Co., and Walgreens Pharmacy.

On March 21, 2025, the defendant Walgreens entities filed an Answer to the Amended Complaint. That same day, OptumRx filed this Motion to Dismiss, arguing plaintiffs' claims against them are preempted by the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 et. seq. ("ERISA"), and that plaintiffs fail to plead a cognizable negligence per se claim. For the reasons that follow, the Motion to Dismiss should be denied.

ARGUMENT

I. Legal Standard

To survive a motion pursuant to Fed. R. Civ. P. 12(b)(6), .a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In determining whether a complaint is sufficient, the court must "construe it in the light most favorable to the nonmoving party, accept well-pleaded facts as true, and draw all inferences in [the non-movant's] favor." *Id*. (quoting *Reger Dev. LLC v. Nat'l City Bank*, 592 F.3d 759, 763 (7th Cir.)). Under this standard, for the reasons set forth below, defendant OptumRx's Motion to Dismiss should be denied.

II. Plaintiffs' Claims are Not Subject to ERISA Preemption.

OptumRx argues that ERISA, a statute intended to make employee benefits "more secure,"[1] prevents Wisconsin from protecting its residents against the abuses that occurred here. This misunderstands both the nature of ERISA and the role of PBMs.

A. ERISA does not regulate PBMs.

ERISA regulates certain private employer and union-sponsored benefit plans. 29 U.S.C. § 1003. PBMs are *not* benefit plans. Rather, benefit plans hire PBMs as service providers that sell plans access to prescription drugs. *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80, 83-90 (2020). PBMs deliver this access by contracting separately with pharmacies to create networks through which plan beneficiaries can fill their prescriptions. *Id.* Because of their unique status, PBMs are not subject to regulation under ERISA.

OptumRx bases its entire preemption argument on the notion that the "plan" and the PBM are one and the same. They are not. PBMs are not "fiduciaries" under ERISA. A person must

[1] *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80, 86 (2020).

exercise "discretionary authority," "control," or "responsibility" over the management or administration of a plan or its assets to qualify as an ERISA "fiduciary." 29 U.S.C. § 1002(21)(A). PBMs do none of these things.

Federal appellate courts are unanimous in holding that PBMs are not ERISA fiduciaries because they do not exercise discretion or control over the administration of ERISA plans.[2] Because PBMs do not qualify as ERISA fiduciaries, they cannot qualify as plan "administrators" either. An "administrator" is a designated fiduciary under ERISA. 29 U.S.C. § 1002(16)(A). As the Department of Labor states, "a plan administrator . . . must, [by] the very nature of his position, have 'discretionary authority or discretionary responsibility in the administration' of the plan." 29 C.F.R. § 2509.75-8(D-3) (citation omitted).

PBMs are third-party service providers that may perform only "ministerial functions" for a plan. *Id*. § 2509.75-8(D-2). Because of their status as non-fiduciaries, PBMs "have no power to make any decisions as to plan policy, interpretations, practices or procedures." *Id.* In *Rutledge*, which is the only U.S. Supreme Court decision on the preemptive effect of ERISA on state regulation of PBMs, the Court emphasized that "state law" governs the goods and services that plans, as market participants, purchase for their beneficiaries. *Rutledge, supra*, at 86-91.

B. Plaintiffs' Claims are not Preempted by ERISA § 514(a).

ERISA includes a preemption clause, 29 U.S.C. § 1144(a). The Supreme Court has held that ERISA preempts state laws that have a "connection with" or "reference to" ERISA plans.

[2] *Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 473 (7th Cir. 2007) (holding that PBMs are not ERISA fiduciaries); *PCMA v. Rowe*, 429 F.3d 294, 300-01 (1st Cir. 2005) (same), *cert. denied*, 547 U.S. 1179 (2006); *accord In re Express Scripts/Anthem ERISA Litig.*, 285 F.Supp.3d 655, 680 (S.D.N.Y. 2018), *aff'd*, 837 F.App'x 44 (2d Cir. 2020), *cert. denied*, 142 S.Ct. 2867 (2022); *Bickley v. Caremark Rx, Inc.*, 361 F.Supp.2d 1317, 1332 (N.D. Ala. 2004), *aff'd*, 461 F.3d 1325 (11th Cir. 2006).

Rutledge, 592 at 86. Here, plaintiffs' claims do not reference or have a connection with an ERISA plan. Moreover, ERISA § 514's savings clause bars preemption here.

1. Plaintiffs' Claims Do Not Reference an ERISA Plan.

OptumRx's brief is striking in its failure to even acknowledge *Rutledge*, a unanimous Supreme Court opinion that sharply limits the scope of ERISA preemption as applied to state regulation of PBMs. Under *Rutledge*, plaintiffs' state law claims do not "reference" an ERISA plan. A state law has an impermissible "reference to" an ERISA plan if it "acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation." *Rutledge*, 592 U.S. 80 at 88. (quotations and citations omitted). That is not the case here.

The Wisconsin statutes at issue, Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a), do not act immediately and exclusively on ERISA plans. Rather, they apply to PBMs whether or not they manage an ERISA plan. *See* Wis. Stat. §§ 632.861(3) (setting forth cost-sharing limitation applicable to disability insurance policy or self-insured health plan), 632.861(4) (setting forth drug substitution provision appliable to disability insurance policy, self-insured health plan, or PBM acting on behalf of disability insurance policy or self-insured health plan), 632.865 (defining PBM as an entity that contracts to administer or manage prescription drug benefits on behalf of an insurer, cooperative, or other entity that provides prescription drug benefits), and 632.866 (provision regarding step therapy protocol established by insurer, pharmacy benefit manager, or utilization review organization). Thus, the statutes do not act "immediately and exclusively" on ERISA plans. *Rutledge v. Pharma. Care Mgmt. Assoc.*, 592 U.S. 80, 88.

In *Rutledge*, the U.S. Supreme Court came to a similar conclusion, deciding that an Arkansas law regulating the price at which PBMs reimburse pharmacies for the cost of prescription drugs covered by health plans "does not act immediately and exclusively upon ERISA plans

because it applies to PBMs whether or not they manage an ERISA plan." *Rutledge,* 592 U.S. 80, 88. The Court noted that the law regulates PBMs "whether or not the plans they service fall within ERISA's coverage" and that "PBMs contract with a variety of healthcare plans and programs that are not covered by ERISA, including Medicaid, Medicare, military, and market place plans." *Id.* at 89 and n.1. *See also Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956 (8th Cir. 2021) (holding North Dakota statute regulating PBMs not preempted as applied to ERISA plans).

Nor does Wisconsin's general common law of negligence act immediately and exclusively on ERISA plans. *See, e.g., Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 831-33 (1988) (holding ERISA did not preempt Georgia's general garnishment statute, which "does not single out or specially mention ERISA plans," even though it was applied to collect judgments against plan participants, and noting that "lawsuits against ERISA plans for run-of-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan – are relatively commonplace."); *Darcangelo v. Verizon Commc'ns, Inc.*, 292 F.3d 181, 191–92 (4th Cir. 2002) (stating "the simple fact that a defendant is an ERISA plan administrator does not automatically insulate it from state law liability for alleged wrongdoing against a plan participant or beneficiary.").

Defendant OptumRx argues that plaintiffs' claims are preempted because the existence of Cole's ERISA plan is essential to adjudicate OptumRx's conduct. That is not the case. It is unnecessary to interpret the plan to see whether Advair Diskus was covered. Rather, plaintiffs' claims arise out of OptumRx's common law negligence and Wisconsin statutory violations in engaging in improper non-medical switching, failing to provide Cole with proper notice, improperly requiring prior authorization and step therapy, and subjecting Cole to an improperly inflated price for Advair Diskus. Any review of the plan would be cursory. *See Kolbe & Kolbe*

Health & Welfare Benefit Plan v. Med. Coll. of Wis., Inc., 657 F.3d 496, 504 (7th Cir. 2011) (state law claim not preempted under ERISA "merely because it requires a cursory examination of ERISA plan provisions."); *Biondi*, 303 F.3d 765 at 780 (common law fraud claim that did not require interpretation or application of plan's provisions not preempted); *Alaska v. Express Scripts, Inc.*, 2024 WL 2321210, *9 (D. Alaska May 22, 2024) (existence of ERISA-covered plans not essential to the State's claims against PBM).

For these reasons, plaintiffs' claims do not "reference" an ERISA plan and cannot be preempted on that basis.

2. Plaintiffs' Claims Do Not have a Connection with an ERISA Plan.

Nor do plaintiffs' claims have an impermissible "connection with" the plan. "Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Rutledge*, 592 U.S. 80 at 87. ERISA is "primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, … or by binding plan administrators to specific rules for determining beneficiary status." *Rutledge*, 592 U.S. 80 at 86-87 (citations omitted). A law may also be preempted if its economic effects "force an ERISA plan to adopt a certain scheme of substantive coverage." *Id*. at 87 (quotation and citation omitted). "[A] shorthand for these considerations" is "whether a state law governs a central matter of plan administration or interferes with nationally uniform plan administration." *Id*. (cleaned up). Curiously, OptumRx's brief never uses the words "central matter of plan administration" or discusses that criteria. Instead, OptumRx offers a different analysis – the claim is preempted if a court must consider the Summary Plan Description to determine OptumRx's duties and whether those duties were met.

In other words, according to OptumRx, ***all*** of its legal duties arise out of the Summary Plan Description and Wisconsin can impose ***no*** other legal duties. But that's not what *Rutledge* says – Wisconsin ***can*** impose additional legal duties on a PBM unless they would "**govern a central matter of plan administration** or interfere with nationally uniform plan administration." *Rutledge*, 592 U.S. 80 at 87 (emphasis added). Put another way, Wisconsin can apply its statutes and common law to regulate PBMs as long as they do not "require plans to provide any particular benefit to any particular beneficiary in any particular way." *Rutledge* at 90. OptumRx never applies this test in its analysis.

Requiring that OptumRx give Cole advance notice of its formulary changes under the facts of this case does not require OptumRx "to provide any particular benefit to any particular beneficiary in any particular way." Nor does a law or standard of care against the non-medical switching that OptumRx forced on Cole here. Neither the Wisconsin statutes nor the common law rules that form the basis of this lawsuit require OptumRx to cover Cole's prescription for Advair Diskus. OptumRx could have complied with either by allowing generic substitution for Advair Diskus. OptumRx could have required Cole to switch drugs if the medical literature supported it. What OptumRx cannot do is switch a patient from a previously covered drug for non-medical reasons *and* not allow a generic substitute. This does not force a PBM to "provide any ***particular*** benefit to any particular beneficiary in any ***particular*** way" because OptumRx had multiple ways to comply. Moreover, because OptumRx's own manual purports to exclude non-medical switching, a ban on non-medical switching does not interfere with "uniform national administration," because OptumRx purports to already apply that standard nationally. Nor does the law preventing OptumRx from dictating a price far in excess of what a person would pay if the drug were not covered by insurance at all mandate any coverage of any drug, it simply limits what can be charged for a non-covered drug.

Preemption does not occur where the application of a state law of general applicability has only a remote connection with an ERISA plan. *See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Company*, 514 U.S. 645 at 661 (1995) (stating preemption does not occur if state law of general applicability has only remote connection with ERISA plan); *Mackey*, 486 U.S. 825, 833 (1988) (noting "lawsuits against ERISA plans for run-of-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan – are relatively commonplace."). The outcome here will not force an ERISA plan to adopt any particular scheme of coverage or dictate plan choices. *Travelers*, 514 U.S. 645 at 668.

Thus, as in *Alaska v. Express Scripts, Inc.*, 2024 WL 2321210, *10 (D. Alaska May 22, 2024), OptumRx "could structure its formularies in the same exact manner as it did prior to this suit," *id.*, as the upshot of plaintiffs' claims is not to govern a central matter of plan administration or interfere with uniform plan administration. As in *Express Scripts*, plaintiffs' claims "are not merely based on the structure of the formularies, but on the manner in which [the PBM] arrived that [sic] their structure: allegedly by ignoring evidence that suggested the need for utilization management due to its financial agreements with manufacturers and desire for profits." *Id*.

Although OptumRx argues that the recent decision in *Cannon v. Blue Cross and Blue Shield of Massachusetts, Inc.*, --- F.4th ----, 2025 WL 855194 (1st Cir. 2025), requires preemption under § 514(a) here, *Cannon* is distinguishable because it was based on a claim for benefit denial, whereas plaintiffs here are suing under three *different* theories: that OptumRx had a statutory and common law duty to inform Cole that both his medication and its generic equivalent would no longer be covered, that OptumRx had a statutory and common law duty not to switch a patient to a different drug unless there was peer reviewed medical literature to support it, and that OptumRx had statutory duty not to require a patient to pay an amount greater than the lowest of either the

cost-sharing amount under the policy/plan or the amount a person would pay if he purchased Advair Diskus at the dispensing pharmacy without using any health plan or insurance coverage.

For these reasons, plaintiffs' claims do not have an impermissible connection to an ERISA plan and cannot be preempted on that basis.

3. ERISA § 514's Savings Clause Also Bars Preemption.

Plaintiffs' claims are also not preempted because they fall within § 514's savings clause, which states "[e]xcept as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance." 29 U.S.C.A. § 1144(b)(2)(a). *See Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985) (holding Massachusetts statute requiring specified minimum mental-health-care benefits not preempted by ERISA because statute fell within scope of the savings clause).

Two factors must be satisfied for a state law to fall within the savings clause. *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 341-42 (2003). "First, the state law must be specifically directed toward entities engaged in insurance." *Id*. at 342 (citation omitted). Second, "the state law must substantially affect the risk pooling arrangement between the insurer and the insured." *Id*.

A state law may be specifically directed toward entities engaged in insurance under the savings clause even if it regulates more than the insurance industry or does not regulate "the actual terms of insurance policies." *Miller*, 538 U.S. 329 at 334-38. Such laws can "focus upon the relationship between an insurer and *third-party providers*" if they regulate insurance "by imposing conditions on the right to engage in the business of insurance." *Id*. at 337-38 (emphasis in original).[3]

[3] It makes no difference that the provisions here may be enforced against third party PBMs, not just insurers themselves. The provisions at issue in *Miller* applied to some "[health maintenance

Plaintiffs' claims based on Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a) are all part of the Wisconsin Insurance Code and are specifically directed at the business of insurance *See* Wis. Stat. §§ 632.861(3) (requiring that a disability insurance policy "that provides a prescription drug benefit or a pharmacy benefit manager that provides services under a contract with a policy … may not require an enrollee to pay at the point of sale for a covered prescription drug an amount that is greater than" as set forth in the statute); 632.861(4) (providing that a disability insurance policy that offers a prescription drug benefit or a pharmacy benefit manager acting on behalf of a disability insurance policy shall provide 30-day notice to an enrollee of certain formulary changes); and Wis. Stat. § 632.866 (imposing clinical review criteria requirements for establishing a step therapy protocol on insurers, pharmacy benefit managers, and utilization review organizations and stating that the commissioner shall promulgate any rules necessary to implement or enforce the section).

The second requirement, that the state law substantially affect the risk pooling arrangement between the insurer and the insured, "does not require that the state law actually spread risk." *Miller*, 538 U.S. 329 at 338, n.3 (citation omitted). For instance, a rule that governs "whether or not an insurance company must cover claims submitted late … dictates to the insurance company the conditions under which it must pay for the risk that it has assumed," which "certainly qualifies as a substantial effect on the risk pooling arrangement between the insurer and insured." *Miller*, 538 U.S. 329 at 338, n. 3. In this case, Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a) satisfy this requirement. *See* Wis. Stat. §§ 632.861(3) (requiring that disability insurance policy may not require an enrollee to pay more than a certain amount for a covered prescription);

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organizations (HMOs)] that do not act as insurers but instead provide only administrative services to self-insured [ERISA health] plans." 538 U.S. at 336 n.1. The Supreme Court determined that the fact that "these noninsuring HMOs [are] administering self-insured plans . . . suffices to bring them within the activity of insurance" for purpose of the insurance savings clause. *Id.*

632.861(4) (notice provision); and Wis. Stat. § 632.866 (imposing clinical review criteria requirements for establishing a step therapy protocol on insurers, pharmacy benefit managers, and utilization review organizations).

The "deemer clause" is an exception created within § 514's savings clause stating that "[n]either an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title … nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer … or to be engaged in the business of insurance … for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies." 29 U.S.C.A. § 1144(b)(2)(B). The deemer clause exempts "self-funded ERISA plans from state laws that 'regulate insurance' within the meaning of the saving clause." *Moran v. Rush Prudential HMO, Inc.*, 230 F.3d 959, 968 (7th Cir. 2000), *aff'd*, 536 U.S. 355 (2002).

Plaintiffs' claims do not fall within the scope of the deemer clause for two reasons. First, OptumRx's misconduct took place, at least in part, while Cole was covered under a fully funded plan in 2023. *See* Amended Complaint at Exhibit "A," ¶¶ 51, 53, 56-60. Indeed, OptumRx's decision to drop Advair Diskus, and its failure to provide Cole with the required notice of the change occurred while Cole was still insured under a fully funded, not self-funded, plan. Second, OptumRx is not the self-insured plan, but a company that contracts with a self-insured plan. As argued by the United States in its amicus brief in *PCMA v. Mulready*[4] (attached as Exhibit "B"), "the deemer clause does not foreclose states from applying their insurance laws to third parties with which plans contract, even where that results in indirect regulation of ERISA plans." *See*

[4] The 10th Circuit's ruling in this case appears at 78 F 4th. 1183 (10th Cir. 2023). After Mulready filed a petition for certiorari, the Supreme Court invited the Solicitor General "to file a brief in this case expressing the views of the United States." 145 S. Ct. 131 (2024).

United States amicus brief in *Mulready* at Exhibit "B," p. 21 n. 4 (citing *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (stating that state laws regulating insurance can be applied to third parties which contract with ERISA plans without ERISA preemption).

Thus, the savings clause is applicable to plaintiffs' claims and they cannot be preempted under § 514(a). Moreover, OptumRx's interpretation of ERISA would lead to anomalous results. ERISA does not generally preempt state licensing statutes. *See, e.g. Benefax Corp. v. Wright,* 757 F. Supp. 800 (W.D. Ky. 1990) (licensing law applied to third party administrator of self-funded plans not preempted by ERISA because they do not "relate to" a plan or at most, any such relationship is tenuous, remote, and peripheral). Wisconsin requires that PBMs be licensed by the insurance commissioner at Wis. Stat. § 632.865(3). It also empowers the insurance commissioner to suspend or revoke that license where the PBM "has repeatedly or knowingly violated an applicable law, rule or order of the commissioner" or "endanger[s] the interests of enrollees or the public." Wis. Stat. § 633.15(2)(b)(1)(b), (c). Under OptumRx's interpretation, it could repeatedly violate Wisconsin insurance law as to ERISA plans, endangering the public, and the commissioner would be powerless to take action against it. If, however, OptumRx acted in the same way with non-ERISA plans, it would be subject to those sanctions. ERISA should not be construed so as to allow such anomalous results.

For all these reasons, plaintiffs' claims are not preempted under ERISA § 514(a) and defendant OptumRx's Motion to Dismiss the Amended Complaint on that basis should be denied.

C. Plaintiffs' Claims are not Preempted by ERISA § 502(a).

ERISA § 502(a) also fails to preempt plaintiffs' claims. A cause of action is preempted if the plaintiff uses state law claims as "an alternative enforcement mechanism to ERISA's civil enforcement provisions, which are delineated in 29 U.S.C. § 1132(a)." *Biondi*, 303 F.3d 765, 776 (7th Cir. 2002). A civil action may be brought under ERISA § 502(a) "by a participant or

beneficiary" to "recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B).

"[T]he first prong of the Supreme Court's test for preemption" under ERISA § 502(a) is whether the plaintiff at some point in time, could have brought his claim under ERISA." *Halperin v. Richards*, 7 F.4th 534, 545 (7th Cir. 2021) (quotation and citation omitted). The claims, relief, and damages plaintiffs seek in the instant action are not available under ERISA. Thus, plaintiffs are not asserting this action "as an end run around" seeking remedies under § 502(a). *Halperin*, 7 F.4th 534, 545 (7th Cir. 2021).[5]

The second prong of the test for preemption under ERISA § 502(a) is whether plaintiffs' cause of action falls within the scope of an ERISA provision that the plaintiffs can enforce via § 502(a), which requires a determination of whether the action may be "properly recharacterized as a suit within the scope of § 502(a)." *Rice v. Panchal*, 65 F.3d 637, 641-642 (7th Cir. 1995). A claim falls within this scope if "(1) the plaintiff complains about the denial of benefits to which he is entitled 'only because of the terms of an ERISA-regulated employee benefit plan'; and (2) the plaintiff does not allege the violation of any 'legal duty (state or federal) independent of ERISA or

[5] ERISA § 502(a) also permits only "suits for legal relief against ERISA plans, administrators, or fiduciaries." *Biondi*, 303 F.3d 765 at 782, citing *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482, 1490 (7th Cir.1996). An issue exists as to whether such a claim could be brought against OptumRx. The Summary Plan Description states Kriete Group is the Plan Administrator and fiduciary, UMR is the claims appeal fiduciary for medical claims and "provides administrative services such as claim payments for medical and pharmacy claims," and OptumRx is a third party administrator for pharmacy claims. *See* Summary Plan Description attached as Exhibit "C," pp. 1-2. It further provides that "Third Party Administrators do not assume liability for benefits payable under this Plan, since they are solely claims-paying agents for the Plan Administrator." *Id.* at p. 1. *See, e.g., Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463 (7th Cir. 2007) (PBM not fiduciary and claim against it could not be sustained under ERISA).

the plan terms[.]'" *Gardner v. Heartland Indus. Partners, LP*, 715 F.3d 609, 613 (6th Cir. 2013) (quoting *Aetna Health Inc. v. Davila*, 542 U.S. 200 at 210 (2004)).

In *Rice*, where an employee sued a plan administrator for medical malpractice "under the state law theory of respondeat superior," the court found his claim was not preempted under ERISA § 502(a) where the plaintiff did "not claim that he did not receive the benefits due to him under the Plan," did not claim "the Plan provide[d] coverage for injuries caused by medical malpractice," and "denied that his claim … rest[ed] upon any express or implied term of the Plan." *Rice*, 65 F.3d 637 at 638, 642. *See also Gardner*, 715 F.3d 609 (claim for tortious interference with contract not preempted under ERISA § 502(a)). Likewise, the instant case is not a claim for improper processing of benefits or the wrongful denial of a covered benefit under the plan. Rather, plaintiffs allege violation of state common law negligence duties and those imposed by Wisconsin statutes, independent of the plan.

Further, the damages sought by plaintiffs do not duplicate, supplement, or supplant the ERISA civil enforcement remedy because plaintiffs do not seek to recover benefits, enforce rights, or clarify rights to future benefits under the terms of the plan. 29 U.S.C. § 1132(a)(1)(B). While "[a]n ERISA § 502(a)(1)(B) claim is essentially a contract remedy under the terms of the plan" that "offers typical contract forms of relief," this is not a contract claim. *Larsen v. United Healthcare Ins. Co.*, 723 F.3d 905, 911 (7th Cir. 2013) (quotations and citations omitted). Rather, plaintiffs seek to recover in tort for their own damages and those suffered by Cole because of defendants' negligent conduct, as described above and in the Amended Complaint.

The third and final prong of the test for preemption under ERISA § 502(a) is whether the plaintiffs' "state law claim cannot be resolved without an interpretation of the contract governed by federal law." *Rice*, 65 F.3d 637, 644. "[C]omplete preemption is required where a state law claim cannot be resolved without an interpretation of the contract governed by federal law," and

thus a suit "by an ERISA plan participant is an action to 'enforce his rights under the terms of a plan' within the scope of § 502(a)(1)(B) where the claim rests upon the terms of the plan or the 'resolution of the [plaintiff's] state law claim ... require[s] construing [the ERISA plan].'" *Rice*, 65 F.3d 637, 644-45 (brackets and ellipses in original) (citation omitted). A state-law tort claim is independent of ERISA when the duty conferred was "not derived from, or conditioned upon, the terms of" the plan and there is no need "to interpret the plan to determine whether that duty exists." *Gardner*, 715 F.3d 609 at 614. In *Gardner*, the court held that a claim for tortious interference with a plaintiff's right to receive benefits under an ERISA plan was not preempted when the court could determine liability without having to interpret any plan terms. *Id*. at 615. As set forth above, plaintiffs' claims here do not require interpretation of the plan but instead arise from the duties attendant to Wisconsin's common law of negligence and statutory provisions. Accordingly, plaintiffs' claims are independent of the plan and are not preempted under ERISA § 502(a).

Under defendant OptumRx's arguments, plaintiffs in the position of Shanon and William Schmidtknecht will have no recourse available for the injury or deaths of their loved ones caused by the negligent conduct of PBMs, and there will be no enforcement mechanism for the Wisconsin statutes intended to protect plan participants from such conduct. Fortunately, that is not the law. For all the foregoing reasons, plaintiffs' claims are not preempted by the ERISA statute and OptumRx's Motion to Dismiss plaintiffs' Amended Complaint on that basis should be denied.

III. Plaintiffs State a Cognizable Claim for Negligence Per Se.

Defendant OptumRx moves for dismissal of plaintiffs' negligence per se claim based on violation of Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a). These are safety statutes intended to protect health plan enrollees from the exact type of harm suffered by Cole Schmidtknecht. OptumRx's violation of these statutes is negligence per se, for which a viable cause of action is stated in the Amended Complaint.

A negligence per se claim may arise from the violation of a safety statute. *Totsky v. Riteway Bus Service, Inc.*, 607 N.W. 2d 637 (Wis. 2000); *Walker v. Bignell*, 301 N.W.2d 447 (Wis. 1981). Wisconsin has recognized as safety statutes "those legislative enactments which are designed to protect a class of persons from a particular type of harm." *Walker*, 301 N.W.2d 447 at 454. Negligence per se arises from violation of a safety statute where three elements are met: 1) the statute was designed to prevent the harm inflicted; 2) the person injured was in the class of persons the statute was designed to protect; and 3) the legislature expressed intent that the statute serve as a basis for civil liability. *Totsky*, 607 N.W. 2d 637, 644. Legislative intent may be implied. *Id*. (requisite legislative intent may be implied from language of statute); *Walker*, 301 N.W.2d 447, 455-56 (same); *Johnson v. Blackburn*, 582 N.W.2d 488, 497 (Wis. Ct. App. 1998), *aff'd but criticized on other grounds*, 595 N.W.2d 676 (Wis. 1999) ("[i]n the absence of a direct expression of legislative intent to create a basis for civil liability, intent may be inferred from the language and the surroundings of the statute.").

That the Wisconsin statutes at issue are safety statutes designed to prevent the harm at issue and Cole was in the class of persons they were designed to protect is evident from both their content and the concerns associated with their development.

The step therapy statute, Wis. Stat. § 632.866 (2019 Wisconsin Act 12), was signed by Wisconsin Governor Tony Evers on July 9, 2019. Its focus on patient safety is apparent on its face, including its reference to step therapy as a protocol establishing "the specific sequence in which prescription drugs for a specified medical condition … are medically appropriate for a particular patient" and its requirements that clinical review criteria be "based on clinical practice guidelines that are derived from peer review publications, evidence-based research, and widely accepted medical practice" and that in "exigent circumstances," defined as "when a patient is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability

to regain maximum function," grant or denial of a request for an exception from step therapy be provided "by the end of the next business day" after an exception request. Wis. Stat. § 632.866(1)(c), (1)(e), (2) and (3)(f).

Official Statements by Wisconsin's Governor and Insurance Commissioner also demonstrate the step therapy law's focus on safety. In a Press Release by Governor Tony Evers, it was noted that the law provided "protection to patients seeking an exception to a step therapy protocol" and placed "some of the control back into the hands of health care providers and patients to decide the best drug treatment regime for a medical condition." July 9, 2019 Press Release, "Gov. Evers Signs Bills Relating to Step Therapy Protocols, In-Home Dialysis Distribution Centers," https://content.govdelivery.com/accounts/WIGOV/bulletins/2505bd0 (last accessed April 9, 2025). The Governor also stated, "we have to continue doing everything we can to make sure that folks in all 72 counties can access the life-saving care they need and deserve without barrier or burden." *Id*. In a separate Release, the Office of the Insurance Commissioner stated that the statute established "a new set of requirements that health insurance companies have to follow when requiring a patient to try a different and less expensive treatment option than the one prescribed by the patient's doctor." *See* October 17, 2019 Press Release, Prescription Drug Step Therapy Changes Go into Effect for Wisconsin Consumers on November 1, at https://oci.wi.gov/Pages/PressReleases/20191017StepTherapy.aspx (last accessed April 9, 2025). Commissioner Michael Afable observed that "[w]hen a patient is prescribed a specific prescription drug by their doctor, they should be confident that they will be able to access that medication or similar one that meets their health care needs." *Id*.

On August 20, 2019, shortly after the enactment of the step therapy law, Governor Evers issued executive Order #39, "Relating to the Creation of the Governor's Task Force on Reducing Prescription Drug Prices," creating a task force to address "excessive prescription drug prices and

the financial burden that prescription drug prices place on Wisconsin residents." Executive Order #39 attached hereto as Exhibit "D." In doing so, Governor Evers recognized not only the skyrocketing price of prescription drugs, but also that many Wisconsin residents "either skip doses or cut pills in half due to the difficulty of affording their medications," that "skipping needed medication due to the unaffordability of prescription drug prices imposes an even greater cost on the health care system as a whole, due to unnecessary physician visits, hospitalization, and use of emergency services," and that "Wisconsinites should be able to afford the prescription medicine they need to lead a healthy life." *Id*.

The Report of the Governor's Task Force on Reducing Prescription Drug Prices was issued in October of 2020. In it, the Task Force recognized that "[d]ue to the high cost of prescription drugs, some individuals are forced to make difficult decisions to ensure access to their medication," including "choosing to ration their medication, potentially putting their health at risk," "not filling a prescription," or "cutting pills in half or skipping a dose." Excerpts from October 2020 Report of the Governor's Task Force on Reducing Prescription Drug Prices, attached hereto as Exhibit "E," at p. 12. One of the Consumer Stories related in the Report was that of a patient with COPD who "was supposed to use his previous inhaler four times a day and had rationed that down to once a day to make his supply last longer. He was charged $385 for that inhaler. His doctor changed him to one where only one dose a day is needed, however the cost is now over $400 a month (before his plan deductible is met)." *Id*. at p. 24. Task Force Membership included Robyn Schumacher, Vice President of Consultant Relations for OptumRx. *Id*. at p. 14.

On March 29, 2021, Gov. Evers signed Wisconsin Senate Bill 3 (2021 Wisconsin Act 9), creating "licensing and practice requirements for pharmacy benefit managers (PBMs) in the State of Wisconsin," including Wis. Stat. § 632.861 (Prescription drug charges), which sets forth the cost-sharing limitation and drug substitution provisions at issue here. WI Gov. Mess., 3/26/2021,

attached hereto as Exhibit "F"; Wis. Stat. § 632.861. The Governor again acknowledged that the "prescription drug supply chain can be a confusing and opaque system that often sends folks jumping through hoops just to access their life-saving medications" and that "[t]his bill takes important steps forward in increasing transparency and looking out for Wisconsin's most vulnerable." *See* WI Gov. Mess. at Exhibit "F."

Not only are Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a) safety statutes designed to protect patients like Cole from the harm at issue in this case, legislative intent that they serve as a basis for civil liability can also be inferred from their language and purpose. *Johnson*, 582 N.W.2d 488, 497 (intent may be inferred from language and surroundings of statute); *Nordeen v. Hammerlund*, 389 N.W.2d 828, 830 (Wis. Ct. App. 1986) (legislative intent that statute become basis for civil liability can be gleaned from statute's clear expression of concern for safety of those it was designed to protect).

The statutes here make PBMs subject to oversight by the Commissioner of Insurance. However, they also set practice standards, do not preclude a private cause of action, and as set forth above, their language and surrounding pronouncements clearly express that they arise out of concern for the safety of those they were designed to protect. *See* Wis. Stat. § 632.866(1)(c), (1)(e), (2) and (3)(f) (language in step therapy law focused on patient safety); July 9, 2019 Press Release, "Gov. Evers Signs Bills Relating to Step Therapy Protocols, In-Home Dialysis Distribution Centers," https://content.govdelivery.com/accounts/WIGOV/bulletins/2505bd0 (referencing focus of step therapy law on patient protection and life-saving care); October 17, 2019 Press Release, Prescription Drug Step Therapy Changes Go into Effect for Wisconsin Consumers on November 1, https://oci.wi.gov/Pages/PressReleases/20191017StepTherapy.aspx (referencing focus on step therapy law on patient's ability to meet their health care needs); Executive Order #39 at Exhibit "D" (recognizing with respect to the development of the task force behind 2021

Wisconsin Act 9 that many Wisconsin residents have difficulty affording the prescriptions they need to lead a healthy life, leading some to skip doses or cut pills in half); October 2020 Report of the Governor's Task Force on Reducing Prescription Drug Prices at Exhibit "E," at pp. 12, 24 (same). Thus, legislative intent that they provide a basis for civil liability may be implied.

This conclusion is supported by the requirement of the Office of the Insurance Commissioner that PBMs provide a performance bond to ensure that administrators fulfill their responsibilities and protect the beneficiaries of employee benefit plans. Specifically, the performance bond must be continuous, issued by an authorized insurer, and payable to the commissioner and any resident beneficiaries of the plans in case of injury caused by the administrator's failure to perform their duties. *See* Wis. Stat. § 633.14(3) (Issuance of license) (stating "[t]he commissioner shall promulgate rules establishing the specifications that a bond supplied by [a] pharmacy benefit manager under sub. (1)(b) or (2)(b) must satisfy to guarantee faithful performance); Wis. Adm. Code § Ins 8.28 (1) (Performance bond requirements) (stating "[a] performance bond required under s. 633.14 (1) (b) or (2) (b), Stats., shall be continuous in form, … shall be in favor of the commissioner and payable to any resident of this state who is the beneficiary of an employee benefit plan administered by the administrator and to any such employee benefit plan on behalf of the residents of this state who are its beneficiaries in the event of injury caused by a failure of the administrator to fulfill its responsibilities as an administrator."). *See also Johnson*, 582 N.W.2d 488 at 497 (legislative intent that statute provide basis for civil liability supported by provision related to owner's liability for failing to hire contractor who is not insured or bonded).

For all these reasons, Wis. Stat. §§ 632.861(3), 632.861(4), and 632.866(2)(a) may be the basis of plaintiffs' negligence per se cause of action. *Antwaun A. ex rel. Muwonge v. Heritage Mut. Ins. Co.*, 596 N.W.2d 456 (Wis. 1999), relied on by defendant OptumRx, does not require a

different outcome. In *Antwaun A.*, a case that arose out of lead poisoning, the Court rejected the plaintiff's negligence per se argument because the facts did not trigger a duty under the statute in question. *Antwaun A.*, 596 N.W.2d 456 at 467. The landlord's obligation to remediate the lead paint was dependent on the issuance of a notice by the Department of Health, which had not been issued. *Id*. Although an ordinance was also at issue in *Antwaun A.*, the court concluded that the ordinance could not be the basis for a civil action not only because it had "scant legislative history" and imposed a fine for violation without mention of civil liability, but also because it "addressed a panoply of regulations ranging from the pedestrian (size of screening mesh, subsection (o)) to the weighty (necessity of having a bathroom, subsection (j))" and was therefore intended to "secure the safety or welfare of the public as an entity" as opposed to the protection of a specific class of persons. *Id*. at 468. To the contrary, here, the history of the statutes establishes that they were concerned with and intended to address the safety and health of a specific class of persons, those such as Cole who receive prescription benefits managed by a PBM.

Likewise, *Cooper v. Eagle River Memorial Hosp., Inc.*, 270 F.3d 456 (7th Cir. 2001), also cited by defendant OptumRx, fails to require dismissal of plaintiffs' negligence per se claim here. In *Cooper*, a medical malpractice case arising out of placental abruption, the plaintiffs argued that the trial court "erred in refusing to provide the jury with a negligence per se instruction based upon [the defendant hospital]'s alleged violation of two provisions of the Wisconsin administrative code" pertaining to the collaboration of advanced practice nurses with physicians and requiring hospitals to maintain written policies for caring for emergency cases. *Cooper*, 270 F.3d 456 at 459-60. The Court of Appeals affirmed the trial court, concluding that the provisions were "clearly regulatory in nature" and not safety statutes because the nursing regulation was "part of a larger chapter governing the certification of advanced practice nurses" and the regulation requiring "hospitals to maintain written policies" did not reveal a clear intent to impose civil liability. *See*

also Leahy by Heft v. Kenosha Memorial Hosp., 348 N.W.2d 607 (Wis. Ct. App. 1984) (nurse licensing statute not safety statute); *McCraw v. Mensch*, 2006 WL 2620344 (W.D. Wis. Sept. 12, 2006) (statute prohibiting practice of law without a license not safety statute). Quite the opposite is true in the instant case, where the statutes at issue evince a concern and intent to protect prescription drug subscribers.

For all these reasons, plaintiffs' Amended Complaint states a viable negligence per se claim and defendant OptumRx's Motion to Dismiss the Amended Complaint on that basis should be denied. Moreover, even if the negligence per se claims are dismissed, the common law negligence claims survive and prevent dismissal of the entire action against OptumRx.

IV. CONCLUSION

For the reasons set forth above, plaintiffs' First Amended Complaint is not preempted by ERISA and also sets forth a claim for negligence per se, and defendant OptumRx, Inc.'s Motion to Dismiss the First Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) should be denied.

Date: April 11, 2025 By: 

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CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below, the foregoing document was electronically filed with the Clerk of Court and served on all counsel of record using the Court's CM/ECF system.

Date: April 11, 2025 By: 

Michael A. Trunk